UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,374	03/09/2007	Calvin Bruce Harley	38797-8004.US00 (510/002)	7952

79975 7590 04/30/2009

King & Spalding LLP
P.O. Box 889
Belmont, CA 94002-0889

EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
04/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,374	HARLEY ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,30-34 and 85-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,30-34 and 85-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/30/2008, 3/11/2009, 3/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-7, 30-34, 83, 84 and 86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for astragaloside IV, cycloastragenol, astragenol, astragaloside IV 16-one, cycloastragenol 6—bethas-D-glucopyranoside and cycloastragenol 3-beta-D-xylopyranoside, does not reasonably provide enablement for the compound of formula I as encompassed by claims 1-7, 30-34, 83, 84 and 86. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompass an enormous number of compounds. Note, for example, that the term “glycoside” is not limited to any specific structural formula of a saccharide and encompasses all monosacchardes, including amino-monosaccharides, disaccharides and oligosaccharides.

(B) The level of predictability in the art.

It is well known in the pharmaceutical art that even minor changes in the structural formula of a compound can lead to major changes in its activity. Note, for example, Table 1 on page 28 of the specification, which shows significant difference in activity of compounds 1-3 and compounds 6-7.

(C) The amount of direction provided by the inventor.

The disclosure of five specific compounds is clearly not commensurate with the full scope of the claimed invention.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which specific compounds will posses the desired telomerase activity, it would take an undue amount of trial and error to test various compounds encompassed by the present claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder et al (U.S. Patent No. 5,770,578) in view of Bodhar et al (Science, vol. 279, 16 January 1998)

Binder et al disclose contacting a cell or tissue with astragaloside (see, for example, claims 4-5 in column 12), but do not disclose identifying a cell or tissue in which an increase in telomerase activity is desired. However, note that Bodhar et al teach that normal human cells undergo a finite number of cell divisions which has an implication in aging and age-related pathologies (page 349). Therefore, Bodhar et al suggest that all animals are in needed of cells or tissue having increased telomerase activity since all animals face aging. Since administration of astragaloside disclosed by Binder et al would inherently result in increased telomerase activity and since telomerase activity is generally desired, the claimed methods are deemed prima facie obvious over the cited prior art.

Claims 88-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder et al in view of Bodhar et al as applied to claims 1-10 above, and further in view of Kitagawa et al (Chem. Pharm. Bull. 31(2), 689-697 (1983)).

Kitagawa et al disclose the related astragaloside and astragenol compounds extracted from Atragali Radix, a known Chinese medicine. It would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to substitute various astragaloside and astragenol compounds in the method

disclosed by Binder et al because such a person would have expected the closely structurally related compounds to have similar activity.

Claims 30-34 and 83-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Binder et al (U.S. Patent No. 5,770,578) or Kitagawa et al (Chem. Pharm. Bull. 31(2), 689-697 (1983)).

Each of Binder et al and Kitagawa et al discloses the claimed compositions comprising astragaloside and/or astragenol compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623